

### **REMARKS**

Reconsideration and withdrawal of the requirement for election of species and rejections of the application respectfully requested in view of the amendments, remarks and enclosures herewith, which place the application in condition for allowance.

#### **I. STATUS OF CLAIMS AND FORMAL MATTERS**

Claims 15-18, 20-25 and 28-32 are pending in this application. Claim 32 has been amended to place it in better condition for Appeal as previously it had read as an independent claim. The claims is now dependent on claim 30 and incorporates one of the elements of claim 31 which greatly reduces the scope of the claim as compared to its original independent form. A Notice of Appeal is being filed concurrently with this response. No new matter has been added by this amendment.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. The amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

#### **II. PROSECUTION HISTORY SYNOPSIS**

This prosecution history background is being provided by the applicants' representative for the benefit of the applicants and the members of the Board of Appeals should this application require an Appeal Brief.

<b>Date</b>	<b>Action Claims pending References used in rejections</b>
25 April 2001	Filing date of application
20 February 2002	<b>First office action on the merits</b> claims 1-13 rejected Kasai (JP 04066509)
19 July 2002	Response to office action claims 14-28 now pending
10 October 2002	<b>Restriction requirement</b>
10 February 2003	Response to restriction requirement claims 14-29 now pending
5 May 2003	<b>Non-final office action (restriction withdrawn)</b> claims 14,15 and 18-28 rejected; claims 16,17 and 29 allowable if rewritten in independent form

	Antipanova et al. (SU 126996)
23 July 2003	Response to office action claims 15-18, 20-25 and 28-32 now pending
4 November 2003	<b>Non-final office action</b> claims 15,17,18,20-25,28 and 30-32 rejected; no rejections for claims 16 and 29 Hirokawa et al. (JP 200344604)
23 February 2004	Response to office action claims 15-18,20-25 and 28-32 still pending
25 April 2004	3-year anniversary date of filing
17 June 2004	<b>Non-final office action</b> claims 15-18,20-25 and 28-32 rejected Nishi et al. (JP 11215004); Yausi et al. (JP 10330202); Kadowaki (JP 10182302); Hasegawa (JP 10182302).
17 December 2004	Response to office action claims 15-18,20-25 and 28-32 still pending
7 April 2005	<b>Final rejection</b> claims 15-18,20-25 and 28-32 rejected (same as 17 June 2004)

## II. THE 35 U.S.C. 102(b) REJECTIONS ARE OVERCOME

Claims 15-18, 28 and 30-32 were rejected as allegedly being anticipated over Nishi et al. (JP 11215004 - "Nishi"); Yausi et al. (JP 10330202 - "Yasui"); Kadowaki (JP 10182302) or Hasegawa (JP 10182302). Reconsideration of this rejection is requested for the following reasons.

MPEP 2131 states in part that "A claim is anticipated only if each and every element set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)" and that "The identical invention must be shown in as complete detail as is contained in the...claim." see *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d, 1913, 1920 (Fed. Cir. 1989). None of the references cited by the Examiner meets the criteria necessary to establish anticipation of the applicants' claimed invention.

As stated earlier, none of the references teaches element b) of the applicants' claim, i.e. that the ALS-inhibitor is dissolved. Therefore, each of the references fails the "all elements" prong needed to establish anticipation. The Examiner argues that the prior art references disclose a composition that is "eventually dissolved in water". However, this position is traversed on several levels:

- (1) Whether an invention is anticipated is a question of fact. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995). The Examiner has provided no evidence beyond his own opinion to support this position.
- (2) The element in question is whether the ALS-inhibitor is dissolved; the fact that the Examiner believes the "composition is eventually dissolved in water" does not speak to the issue of whether the ALS-inhibitor is dissolved.
- (3) None of the references cited by the Examiner teach or suggest the opinion that "composition is eventually dissolved in water" and as such the references fail to show the applicants' claimed invention "in as complete detail as is contained in the...claim".

Such that the Examiner may argue that the ALS is inherently dissolved in the referenced formulations, the Examiner is reminded that MPEP 2112, sec. IV (Requirements of Rejection Based on Inherency; Burden of Proof) states in part that "The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).....To establish inherency, the **extrinsic evidence** 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. **The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**'” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)(citations omitted)" - (emphasis added). Even after five office actions, there is still no extrinsic evidence on the record which would serve to support the position that ALS is inherently dissolved.

Therefore, for any of the reasons cited above, the Nishi, Yausi; Kadowaki or Hasegawa references do not anticipate the applicants' claimed invention.

### **III. THE 35 U.S.C. 103(a) REJECTIONS ARE OVERCOME**

Claims 20-25 were rejected as allegedly being obvious over Nishi et al. (JP 11215004).

Claims 20-25 were rejected as allegedly being obvious over Yausi et al. (JP 10330202).

Claims 20-25 were rejected as allegedly being obvious over Kadowaki (JP 10182302).

Claims 20-25 and 29 were rejected as allegedly being obvious over Hasegawa (JP 10182302).

Given that the response in the final rejection appeared to treat these rejections collectively, the applicants also address the rejections collectively below. Request for reconsideration of the obviousness rejection is made on several grounds.

First, there was no reply to the applicants arguments that none of the cited references served to teach, suggest or motivate the skilled artisan to practice the presently claimed invention. As this is one of basic requirements for establishing a *prima facie* case of obviousness (see MPEP 2143), failure to teach, suggest or provide motivation by the cited reference ends the inquiry and no obviousness can be established. This also means that whatever holding is made by the Examiner with respect to the evidence of secondary condition, i.e. the stability results of Examples I-XIV in Table I would be irrelevant.

Such that the stability results would be a necessary consideration for determining a *prima facie* case of obviousness existed, the Examiner's reliance on inherency of the stability properties could only be asserted if the compositions were truly identical. However, as indicated above, the Examiner has not established that the applicants' claimed invention was anticipated by Nishi, Yausi; Kadowaki or Hasegawa.

#### **REQUEST FOR INTERVIEW**

In the interest of adhering to the tenets of compact prosecution and obtaining good customer service (see page 7 of the FY-2004 Performance and Accountability Report), the applicants request that the teachings of MPEP 707.07(j), sections II and III be applied, especially with regard to the offer of suggestion for correction by the Examiner if the rejections are upheld.

In accordance with MPEP 713.01, section III, should any issue remain as an impediment to allowance, an interview with the Examiner and SPE are respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview ("An interview should normally be arranged for in advance, as by letter, facsimile, electronic mail, telegram or telephone call, in order to insure that the primary examiner and/or the examiner in charge of the application will be present in the office." *Id.*).

**CONCLUSION**

In view of the remarks and amendments herewith, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are earnestly solicited. The undersigned looks forward to hearing favorably from the Examiner at an early date, and, the Examiner is invited to telephonically contact the undersigned to advance prosecution.

Respectfully submitted,  
FROMMER LAWRENCE & HAUG LLP

By: Howard C. Lee  
Marilyn M. Brogan     Howard C. Lee  
Reg. No. 31,233        Reg. No. 48,104  
Telephone:     (212) 588-0800  
Facsimile:     (212) 588-0500